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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 26168 | 7590 | 02/16/2006 | EXAMINER | |
| FISH & RICHARDSON P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | WANG, CHANG YU | |
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1649

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,853

Applicant(s)

SAH, DINAH W. Y.

Examiner

Chang-Yu Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 27, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12, 27-39, 52, and 53 drawn to a method for treating neuropathic pain comprising administering a neublastin peptide, classified in for example class 514, subclass 2.
 - II. Claims 13-26, drawn to a method a method for treating neuropathic pain comprising administering a neublastin peptide and an analgesia-inducing compound, classified in for example class 514, subclass 2.
 - III. Claims 40-51 and 54-56, drawn to a method of reducing the loss of pain sensitivity, classified in class 514, subclass 2.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the analgesia-inducing compound in the Group II is not required in the Groups I and III. In addition, the patient populations and conditions are different in the Groups I-III. The treatments and outcomes are different in Groups I-III. Thus, Inventions I-III are patentably distinct.

Furthermore, in addition to the election of one of the above III groups, further restriction is required under 35 U.S.C. 121 as set forth below to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group:

A. If any one Group from Groups I-III is elected, Applicant is required to elect a single designated molecule selected from a) AA80-AA140 of SEQ ID NO:2, b) AA41-AA140 of SEQ ID NO:2, c) AA1-AA140 of SEQ ID NO:2, d) AA25-AA140 of SEQ ID NO:2, e) AA28-AA140 of SEQ ID NO:2, f) AA80-AA144- of SEQ ID NO:4, g) AA1-AA144 of SEQ ID NO:4, h) AA1-AA224 of SEQ ID NO:5, i) AA81-AA224 of SEQ ID NO:5 j) the C-terminal sequence set forth in either AA107-AA140 of SEQ ID NO:2 or k) AA76-AA140 of SEQ ID NO:2, l) SEQ ID NO:14, m) SEQ ID NO:15, n) SEQ ID NO:16, o) SEQ ID NO:17, p) SEQ ID NO:18, q) SEQ ID NO:19, r) SEQ ID NO:20, s) SEQ ID NO:21, t) SEQ ID NO:22, u) SEQ ID NO:23, v) SEQ ID NO:24, w) SEQ ID NO:25, x) SEQ ID NO:26 or y) SEQ ID NO:27 as recited in claims 8, 22, 47 and 56.

3. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products indicated as group A constitute patentably distinct inventions for the following reasons. Each of the polypeptides has a unique structural feature which requires a unique search of the prior art. The inventions indicated in the group A differ in structure and function as they are composed of divergent amino acids, and the use for each molecule is different. They are also differentially able to bind to other molecules or mediate other biological functions. Therefore, group A constitutes very divergent subject matters indicating that searches

are not co-extensive. A reference to one element would not constitute a reference to another. Searching all of the molecules in a single patent application would provide an undue search burden on the examiner and the USPTO's resources.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated Groups I-III and a single molecular embodiment from designated group A to which the claims will be restricted, even though the requirement is traversed. Applicant is advised that none of Groups I-III and A are species election requirements; rather each of Groups I-III and A are restriction requirements. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups.

Election of Species

6. This application contains claims directed to the following patentably distinct species of the claimed inventions I-III:

7. i. If Group I or Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for a condition associated with neuropathic pain selected from A) post-herpetic neuralgia or B) diabetic neuropathy, C) sciatica, or

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D) tactile allodynia recited in claims 2 and 3 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 13 are generic.

ii. If any one Group from Groups I-III is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for derivative moiety selected from A) aliphatic esters, B) amides, C) N-acyl-derivatives, or D) O-acyl derivatives recited in claims 12, 26, and 51 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3, 13, 15, and 40 are generic.

iii. If Group I or Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for analgesia-inducing compound selected from A) opioids, B) anti-arrhythmics, C) topical analgesics, D) local anaesthetics, E) anticonvulsants, F) antidepressants, G) corticosteroids, H) NSADS, I) gabapentin (1-trimethylomethylcyclohexane acetic acid) or J) pregabalin (S-(+)-4-amino-3-(2-methylpropyl)butanoic acid) recited in claims 13, 15, and 17 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 13 and 15 are generic.

iv. If Group I or Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for anti-cancer agent selected from A) taxol, B)

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taxotere, C) cisplatin, D) nocodazole, E) vincristine, F) vindesine, or G) vinblastine recited in claim 31 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 13 are generic.

v. If Group I or Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for anti-viral agent selected from A) ddI, B) DDC, C) d4T, D) foscarnet, E) dapsone, F) metronidazole, or G) isoniazid recited in claim 33 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 13 are generic.

vi. If Group I or Group II is elected, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for condition associated with neuropathic pain selected from A) Friedreich ataxia, B) familial amyloid polyneuropathy, C) Tangier disease, D) Fabry disease, E) renal insufficiency, F) hypothyroidism, G) vitamin B 12 deficiency, H) vitamin B6 deficiency, I) vitamin E deficiency, J) alcoholism, K) vitamin B6 intoxication, L) hexacarbon intoxication, M) amiodarone, N) chloramphenicol, O) disulfiram, P) isoniazide, Q) gold, R) lithium, S) metronidazole, T) misonidazole, U) nitrofurantoin, V) leprosy, W) Lyme disease, X) Guillain-Barre syndrome, Y) chronic inflammatory de-myelinating polyneuropathy, Z) monoclonal gammopathy of undetermined significance, AA)

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polyneuropathy, BB) trigeminal neuralgia, CC) entrapment syndromes (including but not limited to Carpel tunnel), DD) post-traumatic neuralgia, EE) phantom limb pain, FF) multiple sclerosis pain, GG) reflex sympathetic dystrophy, HH) causalgia, II) neoplasia, JJ) vasculitic/angiopathic neurooathv or KK) idiopathic neuropathv recited in claim 39 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 13 are generic.

8. The species listed above are patentably distinct for the following reasons:

9. These species are distinct because they are different compounds and diseases.

Each specific species of compounds differs with respect to its composition, structural feature, function and use. Consequently the responses of these different biomolecules are also distinct. Further, the molecular mechanisms contributed to the action of each molecule are very different and so are the effects. Thus, these species are patently distinct.

10. For the disease, the etiology and potential molecular mechanisms contributed to these pathological conditions are different. The pathology and etiologies of each pathological condition are very different from each other. The patient populations in each pathological condition and each individual disease in these different categories are also very distinct. For example, the health status, the medication, the diagnosis, and the physiological condition in patients with multiple sclerosis are very different from those with post-traumatic neuralgia. It requires different diagnoses, equipments, steps

and treatments for these different groups of patients. Therefore, each species of diseases is patentably distinct.

11. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a

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single group from designated Groups I-III and a single designated molecule from group A and a single species from groups i-vi that are applicable as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

17. Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is

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(571) 272-4521. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
February 6, 2006


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER